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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ATTACHMENT TO ADVISORY ACTION

Applicants' Amendment

1) Acknowledgment is made of Applicants' after-final amendment filed 03/25/2010 in response to the final Office Action mailed 12/28/09. The amendment has been entered.

Status of Claims

2) Claims 24 and 28 have been amended via the amendment filed 03/25/2010.

Claims 17-22 and 24-30 are pending.

Claims 17-22, 24-28 and 30 are under examination.

Prior Citation of Title 35 Sections

3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Withdrawn

5) The objection to the specification made in paragraph 6 of the Office Action mailed 12/28/09 is withdrawn in light of Applicants' amendment to claims 24 and 28.

Rejection(s) Withdrawn

6) The rejection of claims 24 and 28 made in paragraph 12 Office Action mailed 12/28/09 under 35 U.S.C. § 112, first paragraph, as containing new matter, is withdrawn in light of Applicants' amendment to the claims.

Rejection(s) Maintained

7) The rejection of claims 17-19, 22 and 25 made in paragraph 12 of the Office Action mailed 04/20/09 and maintained in paragraph 8 of the Office Action mailed 12/28/09 under 35 U.S.C § 103(a) as being unpatentable over Granoff *et al*. (*Infect. Immun*. 65: 1710-1715, May 1997, of record) (Granoff *et al*., 1997) in view of Granoff *et al*. (*J. Pediatr*. 121: 187-194, 1992,

of record), Vella *et al*. (*Biotechnology* 20: 1-22, 1992, of record) and Frasch (*In*: *Development and Clinical Uses of Haemophilus B conjugate Vaccines*. (Ed) Willis *et al*. M. Dekker, New York, pages 435-453, 1994, of record), is maintained for the reasons set forth therein and herein below.

Applicants submit the following arguments:

(a) The Office has not established a *prima facie* case of obviousness. The Office has acknowledged that Granoff *et al.,* 1997 does teach the presence of outer membrane vesicles from serogroup B *Neisseria meningitidis* in their immunogenic vaccine composition. Therefore, Granoff *et al.* 1997 provides no information as to the interaction between MF59 and NmB OMVs. (b) Granoff *et al.* 1992 does not teach the presence of MF59 in their immunogenic vaccine compositions. Therefore, Granoff *et al.* 1992 also fails to provide any information regarding the interaction between MF59 and NmB OMVs. (c) MPEP § 2143 states that "combining known prior art elements is not sufficient to render the claimed invention obvious if the results would not have been predictable to one of ordinary skill in the art." One of skill in the art could not predictably combine Granoff *et al.* 1997 with Granoff *et al.* 1992 to produce the instant invention as neither provide any indication of how MF59 and NmB OMVs interact with one another. (c) One of skill in the art would not have been able to predict that combining the Hib-NmB OMV conjugate taught by Granoff *et al.,* 1992 with the MF59 adjuvant taught by Granoff *et al.,* 1997 would result in the expected benefits of using MF59 (see Granoff *et al.,* 1997, right column of page 1714). Indeed Granoff *et al.,* 1997 acknowledge that there was uncertainty regarding using MF59 with polysaccharide-protein conjugate vaccines at last paragraph on left column of page 1714. (d) Given that Granoff *et al.,* 1992 teach a Hib *polysaccharide* conjugated with NmB OMVs, one of skill in the art would not have predicted that the suggested combination of Hib-NmB, NmC-CRM197, and MF59 would work as described in the application at the time the claimed invention was made (*KSR International Co. v. Teleflex Inc*., 127 S.Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (2007)). (e) Applicants cite MPEP 2141.01 III and allege that the Office is using impermissible hindsight to support the rationale of combining the teachings of Granoff *et al.,* 1997 and Granoff *et al.,* 1992. (f) The Office has not demonstrated that *prior* to Applicants' disclosure, one of skill in the art would have combined the teachings of Granoff *et al.,* 1997 and Granoff *et al.,* 1992 to construct the

claimed invention. Neither Granoff reference teaches the use of MF59 with NmB OMVs. Given the unpredictability of using MF59 (right column on page 1714 of Granoff *et al.,* 1997), one of skill in the art would have had no reason to combine PRP-OMP with NmC oligosaccharide and MF59. Without a reason to combine the references, as well as a lack of a predictable result, the only conclusion supported by the record is that the rejection was made impermissibly using hindsight reconstruction of the invention. (g) Claims 18 and 19 require that the capsular oligosaccharide from NmC be conjugated to a protein carrier and that the expected benefit of increased immunogenicity taught by Granoff *et al.,* 1992 would have led one of skill in the art to modify the NmC conjugate of Granoff *et al.,* 1997. (h) The Hib-NmB OMV conjugate elicited earlier acquisition of serum antibody than did the Hib-CRM197 conjugate. Granoff *et al.,* 1992 gives no indication as to whether the NmB OMV would elicit that same early acquisition of antibodies in combination with polysaccharide conjugate (i.e., NmC-CRM197) and an MF59 adjuvant. Given this lack of guidance, one of skill in the art would have been more likely to reduce the number of variables by conjugating NmB OMVs to both Hib and NmC, than to combine PRP-OMP with the NmC-CRM197 and MF59, as suggested by the Office. It would appear that the Office is using the teachings of the present application to support the conclusion that one of skill in the art would have had reason to pick and choose specific elements of the Granoff references to reconstruct the claimed invention. (i) The paragraph cited by the Office refers back to the introduction section on page 1710, which states that MF59 has been used with recombinant glycoprotein subunit vaccines for herpes simplex virus type 2, cytomegalovirus, HIV, and inactivated influenza vaccine. None of the listed vaccines include NmB OMV. (j) Granoff *et al.* 1992 teach that the Hib-OMV conjugate induced increased levels of antibodies after a single dose. However, three doses of the Hib-CRM197 conjugates were required to induce similar levels of antibodies (see Fig. 1). Thus it would be unpredictable whether combining the Hib-OMV conjugate of Granoff *et al.,* 1992 with NmC-CRM197 and MF59 would result in increased levels antibodies after a single injection. (k) The Office has also failed to demonstrate how Vella *et al.* or Frasch impacts the predictability of combining the teachings of Granoff *et al.* 1997 and Granoff *et al.* 1992 to yield the claimed invention.

Applicants' arguments have been carefully considered, but are not persuasive.

The Office has set forth a *prima facie* case of obviousness. The teachings of Granoff *et al*. (1997) as modified by Granoff *et al*. (1992), Vella *et al*. and Frasch taught the claimed composition as set forth previously. Granoff *et al*. (1997) taught an immunogenic combination vaccine composition comprising immunologically effective amounts of group C *Neisseria meningitidis* oligosaccharide-CRM197 conjugate, a *Haemophilus influenzae* b oligosaccharide-CRM197 conjugate, and the generally well tolerated MF59 adjuvant. See 'Materials and Methods'; Results; Figure 1; and page 1710. Granoff *et al*. reported on the most important finding on the augmented or enhanced serum antibody response to both group C *Neisseria meningitidis* and *Haemophilus influenzae* b induced by the MF59 adjuvant. See left column on page 1714. Granoff's (1997) conjugate composition containing MF59 did induce higher capsular antibodies even after the first dose. See last full paragraph on page 1711. Granoff's (1992) Hib-OMV conjugate also induced acceptably high levels of antibodies after three doses. See abstract; Figure 1 and Table II. Granoff *et al.* (1997) indeed suggested the use of MF59 *in combination with other vaccines*. See first full paragraph in right column of page 1714.

Granoff *et al*. (1997) do not teach the presence of the proteosomic vesicles such as outer membrane vesicles from serogroup B *Neisseria meningitidis* in their immunogenic vaccine composition.

However, Granoff *et al*. (1992) taught an immunogenic PRP-OMP conjugate comprising *Haemophilus influenzae* type b (Hib) PRP conjugated to *Neisseria meningitidis* outer membrane protein complex (i.e., OMVs) which was more immunogenic than a conjugate comprising Hib oligomers conjugated to CRM197 after one or two doses. Granoff's (1992) conjugate comprising *Haemophilus influenzae* type b (Hib) PRP conjugated to *Neisseria meningitidis* OMP complex elicited earlier acquisition of serum antibody than the conjugate comprising Hib oligomers conjugated to CRM197 in infants in three geographic regions. See abstract. Granoff's (1992) conjugate comprising *Haemophilus influenzae* type b (Hib) PRP conjugated to *Neisseria meningitidis* outer membrane protein complex (i.e., OMVs) elicited significant increases in serum antibody levels after a single injection at 2 months of age whereas the HbOC conjugate vaccine required additional doses at 4 and 6 months of age to elicit a comparable antibody response. Granoff *et al*. (1992) expressly taught that the OMP carrier has been reported to have adjuvant properties for both T cell-dependent and T cell-independent antigens and has also been reported to

be mitogenic unlike the CRM carrier protein used in HbOC conjugate vaccine. See the paragraph bridging pages 191 and 192. That the PRP-OMP or PRP-OMPC conjugate, is known by the commercial name PedvaxHIB, and that it comprises *Hib capsular oligosaccharides* conjugated to the outer membrane protein complex or OMPC (i.e., OMVs) obtained from serogroup B *Neisseria meningitidis* by deoxycholate extraction process is implied in the prior art teachings in light of what is known in the art. For example, Vella *et al*. taught that the PRP-OMPC conjugate is known by its commercial name, PedvaxHIB, and that it comprises OMVs from serogroup B *Neisseria meningitidis* obtained by deoxycholate extraction process. See the last paragraph on page 3; and Table 1-1. Liekwise, Table 1 and section V on page 444 of the Frasch reference taught that the FDA-approved Merck Hib PRP-OMPC vaccine, also known as PRP-OMP or PedvaxHIB, comprises *size-reduced polysaccharide* (i.e., *oligosaccharide*) of Hib conjugated to meningococcal outer membrane *vesicles*. Frasch further characterized the Hib PRP-OMPC vaccine as having a number of *unique* properties such as induction of a strong immune response in infants after the first dose, and the OMV protein carrier not being a component of the DTP vaccine. See section V of Frasch. Therefore, Applicants' statement that Granoff *et al.,* 1992 teach a Hib *polysaccharide* conjugated with NmB OMVs is incorrect.

As set forth previously, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to replace the *Haemophilus influenzae* b oligosaccharide-CRM197 conjugate in Granoff's (1997) immunogenic combination vaccine composition with Granoff's ('1992) more immunogenic PRP-OMP conjugate comprising *Haemophilus influenzae* type b (Hib) oligosaccharide conjugated to *Neisseria meningitidis* OMVs, which was known in the art to elicit earlier acquisition of serum antibody than a conjugate comprising Hib oligomers conjugated to CRM197 as taught by Granoff *et al*. (1992), to produce the immunogenic composition of the instant invention. One of ordinary skill in the art would have been motivated to produce the instant invention for the expected benefit of providing a combination conjugate vaccine that includes a Hib conjugate that is more immunogenic than a conjugate comprising Hib oligomers conjugated to CRM197 after one or two doses and that advantageously elicits earlier acquisition of serum antibody than the conjugate comprising Hib oligomers conjugated to CRM197 in infants in three geographic regions Granoff *et al*. (1992), *or* that has a number of *unique* properties such as induction of a strong immune response in infants

after the first dose, and the OMV protein carrier not being a component of the DTP vaccine as taught by Frasch.

Thus, the Office has clearly demonstrated that *prior* to Applicants' disclosure, the claimed invention would have been obvious to one of ordinary skill in the art. Sufficient reasoning has been set forth in paragraph 12 of the Office Action mailed 04/20/09 to establish a *prima facie* case of obviousness. One of skill in the art would have produced the instant invention as set forth in the rejection of record given the express suggestion in cited prior art, the art-known adjuvant function of MF59, and the art-demonstrated success of adding MF59 to combined multivalent conjugate vaccines. The art-known MF59 would have been expected to enhance the immunogenicity of one or more components present in Granoff's (1997) composition as modified by Granoff *et al*. (1992), Vella *et al*. and Frasch. The uncertainty allegedly taught by Granoff *et al*. (1997) is not an issue since the rejection of record does not suggest adding DTP to produce the instant invention. One of ordinary skill in the art would have readily understood that the OMPC-containing composition of Granoff *et al*. (1992) does not contain DTP or DTaP vaccine that contains diphtheria toxoid, and therefore is a beneficial non-diphtheria toxoid component to use in Granoff's (1997) composition in addition to it having a number of *unique* properties such as induction of a strong immune response in infants after the first dose as taught by Frasch.

Contrary to Applicants' assertion, in the last paragraph on left column of page 1714, Granoff *et al*. (1997) do not teach uncertainty regarding using MF59 with polysaccharide-protein conjugate vaccines. The last paragraph on left column of page 1714, Granoff *et al*. (1997) is reproduced below [Emphasis added]:

> Because only small numbers of infant baboons could be investigated, many important questions such as the optimal conjugate vaccine dose when given with MF59 or the optimal immunization schedule could not be addressed. … we did not examine the influence, if any, of simultaneous separate injections of other vaccines, such as DTaP or diphtheria-tetanus-pertussis, that contain diphtheria toxoid, which might influence serum anticapsular antibody responses to conjugate vaccines containing CRM197, a nontoxic mutant of diphtheria toxin. This question will be important to investigate in the future, since in previous studies, immunity to the carrier protein was shown to affect (*positively* or negatively) the ability to mount anti-PS antibody responses to conjugate vaccines (11, 14, 28, 34).

The above-cited paragraph from Granoff *et al*. (1997) indicates no uncertainty regarding using MF59 with polysaccharide-protein conjugate vaccines. This part of Granoff *et al*. (1997) pertains to simultaneous separate injections of DTaP or diphtheria-tetanus-pertussis that contain diphtheria

toxoid, which has no relevance to the instant rejection of record, since Granoff's (1992) *Haemophilus influenzae* type b (Hib) oligosaccharide conjugated to *Neisseria meningitidis* outer membrane protein complex (i.e., OMVs) does not contain diphtheria-tetanus-pertussis vaccine containing diphtheria toxoid. Moreover, Granoff *et al.* (1997) are only stating what they did not examine, but what one should investigate in the future, which in no way conveys uncertainty regarding the use of MF59 with polysaccharide-protein conjugate vaccines. In fact, Granoff *et al.* (1997) had already established at the time of the invention that MF59 could successfully be combined with a multivalent combination vaccine comprising more than one carbohydrate-containing elements and protein elements. The paragraph from right column of page 1714 of Granoff *et al.* (1997) pointed to by Applicants is reproduced below [Emphasis added]:

> In summary, *the excellent immunogenicity* of *N. meningitidis* group C and Hib conjugate vaccines when administered with MF59 to infant baboons and *the lack of apparent toxicity* are consistent with the excellent immunogenicity and safety record of *MF59 used with other vaccines in clinical trials in humans* (summarized in the introduction). These data, together with the potential of an adjuvant either to permit the use of lower conjugate vaccine dosages and/or fewer injections **or** to enhance the immunogenicity of multicomponent PS-protein conjugate vaccines given alone or *in combination with other vaccines, support the initiation of phase I safety and immunogenicity trials of MF59 and glycoconjugate vaccines in humans.*

From this, one of skill in the art would not conclude unpredictability of combining the Hib-NmB OMV conjugate of Granoff *et al.,* 1992 with the MF59 adjuvant taught by Granoff *et al.,* 1997. Instead, one would be encouraged to produce the invention as set forth in the rejection of record, since Granoff *et al.* (1997) had already demonstrated that MF59 added to multicomponent combination vaccines enhances the immunogenicity of the vaccines. In response to Applicant's argument that the Office's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case, the knowledge was well within the level of ordinary skill at the time the claimed invention as set forth above. One of skill in the art would have minimally expected the MF59 adjuvant to predictably enhance the immunogenicity of one or more components of Granoff's (1997) composition as modified by Granoff *et al*. (1992), Vella *et al*. and Frasch.

Applicants appear to argue that the combination of references fail because the prior art does not have anticipatory references regarding all elements of the invention. The argument is not persuasive. At issue is whether the claimed immunogenic composition is obvious over the prior art composition, given the teaching of the applied prior art references. As explained above, the invention as a whole, would have been *prima facie* obvious to a practitioner in view of the knowledge in the art at the time of invention, the state of the art at the time of the invention, and the combined teachings of Granoff *et al*. (1997), Granoff *et al*. (1992), Vella *et al*. and Frasch. It should be noted that what would reasonably have been known and used by one of ordinary skill in the art need not be explicitly taught. See *In re Nilssen*, 851 F.2d 1401, 7 USPQ2d 1500 (Fed. Cir. 1988). In the instant case, the cited references provide sufficient reason, suggestion, and/or motivation to combine their teachings. The test of obviousness is not express suggestion of the claimed invention in any and all of the references, but rather what the references taken collectively would reasonably have suggested to those of ordinary skill in the art presumed to be familiar with them. *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). Obviousness does not require absolute predictability (see *In re Lamberti*, 192 USPQ 278), but only a reasonable expectation of success (see *In re O'Farrell*, 7 USPQ 2d 1673, Fed. Cir. 1988). The rejection stands.

With regard to Applicants' remarks on the rejection of claims 18 and 19, it should be noted that the independent claim 17 recites a generic 'carrier' which encompasses a plethora of isolated and non-isolated, purified and non-purified protein and non-protein carriers within its incredibly broad scope. The limitation 'a protein carrier' in claim 18 encompasses a plethora of isolated and non-isolated, purified and non-purified protein carriers other than CRM_{197}. Applicants have provided absolutely no guidance or information as to the interaction between MF59 and a generic 'carrier' or a generic 'protein carrier'. Claims 18 and 19, which encompass the CRM_{197} protein carrier, are obvious over the prior art for reasons already of record. Furthermore, the Office has clearly set forth the relevance of the teachings of Vella *et al.* and Frasch to the rejection of record. The rejection stands.

8) The rejection of claim 21 made in paragraph 13 of the Office Action mailed 04/20/09 and maintained in paragraph 9 of the Office Action mailed 12/28/09 under 35 U.S.C § 103(a) as being unpatentable over Granoff *et al*. (*Infect. Immun*. 65: 1710-1715, May 1997, of record)

(Granoff *et al*., 1997) as modified by Granoff *et al*. (*J. Pediatr*. 121: 187-194, 1992), Vella *et al*. (*Biotechnology* 20: 1-22, 1992) and Frasch (*In*: *Development and Clinical Uses of Haemophilus B conjugate Vaccines.* (Ed) Willis *et al*. M. Dekker, New York, pages 435-453, 1994) as applied to claim 17 above, and further in view of Dalseg *et al.* (*In*: *Vaccines* 96. (Ed) Brown F. Cold Spring Harbor Laboratory Press, Cold Spring Harbor, N.Y., pages 177-182, 1996, of record), is maintained for the reasons set forth therein and herein below.

Applicants contend that the Office has not established a *prima facie* case of obviousness because the Office has not shown that combining the teachings of the references would yield a predictable result. The Office has not demonstrated how Dalseg *et al.* impacts the predictability of combining the teachings of Granoff *et al.* 1997 and Granoff *et al.* 1992 to yield the claimed invention.

Applicants' arguments have been carefully considered, but are not persuasive. As set forth *supra*, the Office has established a *prima facie* case of obviousness with regard to the teachings of Granoff *et al*. (1997) as modified by Granoff *et al*. (1992), Vella *et al*. and Frasch. In paragraph 13 of the Office Action mailed 04/20/09, the Office has clearly set forth therein how Dalseg's teachings are relevant to the rejection of record. The rejection stands.

9) The rejection of claim 24 made in paragraph 14 of the Office Action mailed 04/20/09 under 35 U.S.C § 103(a) as being unpatentable over Granoff *et al*. (*Infect. Immun*. 65: 1710-1715, May 1997, of record) (Granoff *et al*., 1997) as modified by Granoff *et al*. (*J. Pediatr*. 121: 187-194, 1992, of record), Vella *et al*. (*Biotechnology* 20: 1-22, 1992) Frasch (*In*: *Development and Clinical Uses of Haemophilus B conjugate Vaccines*. (Ed) Willis *et al*. M. Dekker, New York, pages 435-453, 1994) as applied to claim 17 above, and further in view of Seid (US 6,638,513, of record) ('513) or Granoff (WO 98/58670) ('670), is maintained for the reasons set forth therein and herein below.

Applicants contend that the Office has failed to establish a *prima facie* case of obviousness because the Office has not shown that combining the teachings of the references would yield a predictable result. Applicants allege that the Office has not demonstrated how Seid ('513) or Granoff ('670) impacts the predictability of combining the teachings of Granoff *et al*. (1997) and Granoff *et al*. (1992) to yield the claimed invention.

Applicants' arguments have been carefully considered, but are not persuasive. As set forth *supra*, the Office has established a *prima facie* case of obviousness with regard to the teachings of Granoff *et al*. (1997) as modified by Granoff *et al*. (1992), Vella *et al*. and Frasch. In paragraph 14 of the Office Action mailed 04/20/09, the Office has clearly set forth therein how Seid's ('513) or Granoff's ('670) teachings are relevant to the rejection of record. The rejection stands

Remarks

10) Claims 17-19, 21, 22, 24 and 25 stand rejected.

Claim 20 is objected to as being dependent from a rejected claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 26-28 and 30 are allowable.

11) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

13) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

14) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Robert Mondesi, can be reached on (571) 272-0956.

/S. Devi/
Primary Examiner
AU 1645

April, 2010